REMARKS

I. Status of the Claims

Claims 1-63 were originally filed. In response to a restriction requirement, claims 1-18, 34, 35, and 61-63 were elected, whereas the remaining claims were withdrawn and later canceled. Claims 2, 3, 7, 9-18 were further canceled. Upon entry of the present amendment, claims 1, 4-6, 8, 34, 35, and 61-63 remain pending.

Claims 1 and 61-63 have been amended to recite that the receptor "binds glutamate," support for which can be found in the specification, *e.g.*, on page 8, lines 8-12. Claims 1 and 61-63 have also been amended to recite "an amino acid sequence having at least 80% sequence identity to SEQ ID NO:1, SEQ ID NO:2, or SEQ ID NO:3," and new claims 64-67 have been added to recite "an amino acid sequence having at least 90% sequence identity to SEQ ID NO:1, SEQ ID NO:2, or SEQ ID NO:3," which finds support in the specification, *e.g.*, on page 12, lines 11-14. No new matter is introduced.

II. Claim Rejections

A. 35 U.S.C. §112, First and Second Paragraphs: "Glutamate Ligand"

Claims 1, 4-6, 8, 34, 35, and 61-63 were rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness, and under 35 U.S.C. §112, first paragraph, for alleged lack of written description. Specifically, the Examiner asserted that the phrase "glutamate ligand" is unclear as to what it encompasses and lacks support in the specification.

In response, claims 1 and 61-63 are amended to replace the phrase "a glutamate ligand" with "glutamate," which finds support in the specification, *e.g.*, on page 8, lines 8-12. Applicants submit that "glutamate" refers to a single chemical compound of definitive identity and there is no ambiguity associated with this term. The rejections of pending claims under 35 U.S.C. §112, first and second paragraphs, for reciting the phrase "glutamate ligand" is thus overcome.

B. 35 U.S.C. §101: Utility Rejection

The Examiner sustained the rejection of claims 1, 4-6, 8, 10, 11, 13, 17, 18, 34, 35, and 61-63 under 35 U.S.C. §101 for alleged lack of utility. Applicants respectfully traverse the rejection.

The present invention relates to the identification of G-protein coupled receptor B3 (GPCR-B3), a GPCR expressed specifically in taste cells. It is asserted in the specification that this taste cell specific GPCR is a component of the taste signal transduction pathway and is capable of, via its interaction with a G-protein, mediating taste (such as sweet, bitter, unami, *etc.*) perception. *See, e.g.*, page 3, lines 7-10; page 3, line 31, to page 4, line 2; and page 9, lines 30-33, of the specification. It is further asserted that GPCR-B3 polypeptides or the encoding nucleic acids can be used, for example, as probes to identify taste cells, to generated taste topographic map, and to provide a screening method for compounds that can modulate taste signaling and are therefore useful in the food and pharmaceutical industries. *See, e.g.*, page 8, line 16, to page 9, line 10, of the specification.

In addition, Applicants previously submitted Dr. Zuker's declaration under 37 C.F.R. §1.132 (along with Applicants' response of September 16, 2002). In this declaration, Dr. Zuker attests that given the structure and expression pattern of GPCR-B3, as well as the results of a functional assay using a chimeric GPCR construct, one of skill in the art would readily recognize, at the time this application was filed, the immediately available of use of the claimed GPCR-B3 polynucleotides or polypeptides, *e.g.*, for identifying modulators of taste signal transduction. It is thus established an ordinarily skilled artisan would find the asserted utility specific, substantial, and credible.

In the November 22, 2002, final Office Action, the Examiner took the position that the GPRC-B3 polypeptide lacks substantial utility, or a "real world" use, because the polypeptide is not described as to be involved in any particular aspect of the taste perception. In response, Applicants submitted on October 23, 2003, the reference by Nelson *et al.*, which shows that GPCR-B3 (also known as T1R1), forming a heterodimeric GPCR with T1R3 and functioning as an L-amino acid taste receptor, is indeed involved in a definitive aspect of the

taste perception. In the June 28, 2004, Office Action, however, the Examiner dismissed the Nelson *et al.* reference, stating that since the presence of GPCR-B3 in this heterodimeric receptor is described only in this reference but no in the present specification, one of skill in the art would not recognize or believe such use of GPCR-B3 after reading the specification. Applicants cannot agree with the Examiner's reasoning.

According to MPEP §2107, the Examiner should review the claims and the supporting written description to determine whether the utility requirement under 35 U.S.C. §101 is met. No rejection based on lack of utility should be made if an applicant has asserted a specific and substantial utility that would be considered credible by one of ordinary skill in the art.

In most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. §101. MPEP §2107.02 III A. The Court of Customs and Patent Appeals stated in *In re Langer*:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of §101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 183 USPQ 288, 297 (CCPA, 1974, emphasis in original). To overcome the presumption of sufficient utility as asserted by an applicant, the Examiner must carry the initial burden to make a *prima facie* showing of lack of utility and provide a sufficient evidentiary basis for the conclusion. In other words, the Examiner "must do more than merely question operability--[he] must set forth factual reasons which would lead one skilled in the art to question objective truth of the statement of operability." *In re Gaubert*, 187 USPQ 664, 666 (CCPA 1975).

In the present case, Applicants have asserted a specific and substantial utility in the specification and submitted Dr. Zuker's declaration to demonstrate that this asserted utility is credible to one of skill in the art. In contrast, the Examiner has not provided any evidence or

objective reason to overcome the presumed patentable utility. The Nelson *et al.* reference was provided merely as an example of confirmed involvement of GPCR-B3 in taste signaling. On the other hand, it is possible that GPCR-B3 can act alone or in complex with other proteins including other GPCRs to mediate taste signal transduction. The Nelson reference was not cited by any means to indicate or suggest that GPCR-B3's sole involvement in taste perception is via complexing with T1R3 to form a heterodimer. This reference was cited to demonstrate the credibility of the asserted utility that GPCR-B3 is involved in taste signaling and is therefore useful in, *e.g.*, screening methods for identifying taste-modulating compounds. Thus, whether or not the specification describes this heterodimer of GPCR-B3 and T1R3 is not directly relevant to whether one of skill in the art would find the asserted utility credible. In fact, the notion that one of skill in the art would, at the time this application was filed, find the asserted utility credible has already been established by Dr. Zuker's declaration and not yet rebutted by the Examiner.

Accordingly, Applicants respectfully submit that the rejection based on alleged lack of utility should be properly withdrawn.

C. 35 U.S.C. §112 First Paragraph: Utility-Based Enablement Rejection

The rejection of claims 1, 4-6, 34, 35, and 61-63 under 35 U.S.C. §112, first paragraph, was also sustained for alleged inadequate enablement. The Examiner stated that since the claimed invention has no patentable utility, one of skill in the art would not know how to use the invention. As discussed above, the instant invention meets the utility requirement under 35 U.S.C. §101. Applicants therefore respectfully request that the utility-based enablement rejection be withdrawn.

The Examiner further alleged that the specification fails to teach how to get a polypeptide of SEQ ID NO:1, 2, or 3 to bind glutamate, or any other ligand, or to induce GPCR activity. Applicants disagree with the Examiner. First of all, signal transduction in taste cells has been the focus of numerous studies and one of skill in the art would know, at the time this application was filed, the general conditions under which to conduct this type of experiments to test the binding between a claimed polypeptide and glutamate or to test GPCR activity. This is evidenced by the references that are cited throughout the specification, *e.g.*, on page 3, lines 7-

13, and the knowledge about GPCR and various tastants provided therein. Secondly, the specification also offers detailed description on how to examine the interaction between a claimed GPCR polypeptide and a ligand such as glutamate as well as to test the GPCR activity (*see, e.g.*, from page 41, line 25, to page 47, line 10), which, when combined with what's known in the art, fully allows a skilled artisan to test the binding of glutamate and the induction of GPCR activity.

Accordingly, Applicants contend that the claimed invention is fully enabled and the enablement rejection should be properly withdrawn.

D. 35 U.S.C. §112 First Paragraph: Written Description Rejection

The Examiner further maintained the rejection of claims 1, 6, 34, 35, and 61-63 under 35 U.S.C. §112, first paragraph, for alleged inadequate written description. Applicants respectfully traverse the rejection in light of the present amendment.

Possession of claimed invention may be shown by a variety of descriptive means, including words, structure, figures, diagrams, and formulas. MPEP §2163 I. Case law provides more specific guidance in setting the standard for written description.

The amended claims are directed to an isolated nucleic acid that can hybridize to a structurally defined polynucleotide sequence under specified highly stringent conditions and encodes a taste transduction G-protein coupled receptor, which binds to glutamate and becomes activated. The amended claims fully comply with the requirements for written description of a chemical genus as set forth in *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). As described by the Federal Circuit in *Lilly*, "[a] description of a genus of cDNAs may be achieved by means of . . . a recitation of structural features common to the members of the genus . . . ." *Lilly*, 43 USPQ2d at 1406. Furthermore, the court in *Fiers v. Revel* stated that an adequate written description "requires a precise definition, such as by structure, formula, chemical name, or physical properties." *Fiers*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993).

On the other hand, proper description of functional features of a claimed invention can play an important role in satisfying the written description requirement. The

Federal Circuit recently stated that "*Lilly* did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure." *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 65 USPQ2d 1385, 1398 (Fed. Cir. 2003).

With regard to the claimed nucleic acids, pending claims set forth both functional features, *e.g.*, encoding a taste transduction GPCR that binds to and becomes activated by glutamate, and structural features, *e.g.*, encoding a GPCR comprising an amino acid sequence having a certain percentage identity to a reference amino acid sequence.

The percentage sequence identity of a polypeptide to a reference amino acid sequence is a physical/structural property of the nucleic acid encoding the polypeptide, because the amino acid sequence of the polypeptide is determined by the polynucleotide sequence of the nucleic acid. Thus, pending claims set forth commonly shared structural features of the claimed nucleic acids by describing the percentage amino acid sequence of the polypeptides encoded by the nucleic acids.

Commonly shared functional features of the claimed nucleic acids are also provided: each encodes a taste transduction GPCR that can bind to and become activated by glutamate. These functional features can be readily tested and verified by one of ordinary skill in the art using well established, routinely practiced techniques as well as according to the teaching of the present specification (*see, e.g.*, page 41, line 25, to page 47, line 10).

Thus, both structural and functional features commonly shared by the claimed genus have been described in detail, which "clearly allow persons of ordinary skill in the art to recognize that [the applicant] invented what is claimed." *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). Such description is consistent with the standards set forth in both *Lilly* and *Amgen*.

In concluding that the claims are not adequately described, the Examiner stated that "[t]he skilled artisan appreciates that simply writing down or verbalizing that an unknown

protein should have a definite function in no way places one in possession of such a protein. Nor does the writing down of hybridization conditions put one in possession of a polynucleotide encoding such a protein" (the paragraph bridging pages 5 and 6 of the June 28, 2004, Office Action). Applicants contend that the Examiner's position is without the support of either the MPEP or the case law. 35 U.S.C. §112, first paragraph, requires a specification to describe a claimed invention in such detail that one of skill in the art can reasonably conclude that the applicant had in his possession the claimed invention at the time the application was filed. On the other hand, the case law provides more specific guidance on how this requirement may be satisfied. Based on the written description analysis that is provided in the previous sections and following the reasoning of the prevailing case law, Applicants submit that the claimed invention is properly and sufficiently described. Yet, the Examiner rejects the pending claims for alleged inadequate written description without offering any specific reason or analysis under the MPEP or the case law. Applicants do not believe that a written description rejection made in such a conclusory manner is consistent with the requirement of the MPEP.

In summary, based on the analysis under *Lilly* and *Amgen* provided above, Applicants believe the claimed invention within the current claim scope is properly described by the specification under 35 U.S.C. §112 first paragraph. As such, the withdrawal of written description rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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